

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 865 800 A2

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
23.09.1998 Bulletin 1998/39

(51) Int Cl.⁶: **A61N 1/05**

(21) Application number: **98301945.6**

(22) Date of filing: **16.03.1998**

(84) Designated Contracting States:
**AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC
NL PT SE**
Designated Extension States:
AL LT LV MK RO SI

• **Camps, Antoine N.J.M.**
6287 NJ Eys (NL)
• **Van Der Kruk, Ron**
6241 CK Bunde (NL)

(30) Priority: **17.03.1997 US 820473**

(71) Applicant: **MEDTRONIC, INC.**
Minneapolis, Minnesota 55432 (US)

(74) Representative: **Hughes, Andrea Michelle et al**
Frank B. Dehn & Co.,
European Patent Attorneys,
179 Queen Victoria Street
London EC4V 4EL (GB)

(72) Inventors:
• **Woloszko, Jean**
San Diego, California 92130 (US)

(54) Medical electrical lead

(57) A medical electrical lead for establishing an electrical connection with a tissue of the body, the lead having a lead body 6 and a semi-cylindrical cuff 15. In the preferred embodiment the semi-cylindrical cuff features one or more electrodes 10, 11, 12. The semi-cylindrical cuff having a long flap 16 which wraps about the cuff and a short flap 17 which wraps about the long flap. The semi-cylindrical cuff is relatively stiff as compared to the short flap. The short flap, in turn, is relatively the same stiffness as the long flap. The stiffness of each flap may be varied, however, so that one is more or less than the other, and in turn, than the cuff. Through such a multi-flap construction the electrodes may be positioned proximal to a nerve in such a manner that the mechanically induced damage may be minimized or even entirely eliminated. Finally, a method of implanting such an electrode is also disclosed.

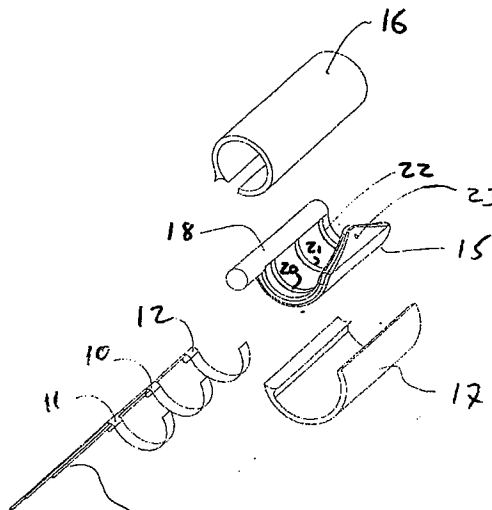


Fig 4A

Description

This invention relates to the field of body-implantable medical device systems, and in particular to a medical electrical lead which features a semi-cylindrical cuff designed to stimulate or sense or both nerve tissue.

Modern electrical therapeutic and diagnostic devices, such as pacemakers or nerve stimulators for example, require a reliable electrical connection between the device and the body. In cases of nerve stimulators, in particular, chronically reliable electrical connections have been difficult to attain. In a chronic setting it has been found many medical electrical leads may damage a nerve either mechanically or electrically or both.

Mechanically induced damage includes thickened epineurium due to accumulation of connective tissue between the electrode and the nerve, increased subperineural and endoneural connective tissue, endoneural edema, demyelination, axonal degeneration and frank axonal loss. Such damage may be caused in several ways. First, if the lead and in particular the electrode which interfaces with the nerve does not move with the nerve, then abrasion may result. Second, the presence of the lead and in particular the electrode, a foreign object, may cause edema or swelling of the nerve. As the nerve swells it may be constricted by the lead. A compressive force may thereby be induced upon the nerve. In the past a so called "self-sizing" nerve electrode was fashioned to avoid such damage. Such an electrode may be seen in the U.S. Patent No. 4,920,979 to Bullara entitled "Bidirectional Helical Electrode for Nerve Stimulation and assigned to the Huntington Medical Research Institute. To date, however, such electrodes have not been wholly satisfactory.

Electrically induced damage may also be caused by a chronic nerve electrode. Such damage results in, among other injuries, axonal degeneration as well as nerve edema. While it has been shown that the type of electrical stimulation, e.g. frequency, waveform, amplitude, may be a significant factor, the actual electrode design may also affect the degree of electrically induced damage. In particular a medical lead which provides the optimal electrical characteristics for the desired therapy is needed.

The present invention provides a medical electrical lead for establishing an electrical connection with a tissue of the body. The present invention is particularly suited for use as a nerve electrode and essentially comprises a lead body and a semi-cylindrical cuff.

According to one aspect of the invention, there is provided a medical electrical lead comprising a lead body having a conductor covered by an insulator, the lead body having a proximal end and a distal end; means for connecting the lead body to a pulse generator, the connecting means coupled to the proximal end of the lead body, a cuff assembly coupled to the distal end of the lead body, the cuff assembly having a root portion, a semi-cylindrical cuff extending from the root

portion in a first radial direction and a long flap extending from the root portion in a second radial direction, the long flap extending over at least a portion of the semi-cylindrical cuff.

According to another aspect, there is provided a medical electrical lead comprising: a lead body having a conductor covered by an insulation, the lead body having a proximal end and a distal end; a cuff assembly coupled to the distal end of the lead body, the cuff assembly having a semi-cylindrical cuff having at least one recess therein, a tab electrode positioned at the bottom of the or each recess, the tab electrode coupled to the conductor.

According to another aspect, there is provided a system for providing medical electrical stimulation comprising: one or more medical electrical leads having a lead body and an electrode portion, the electrode portion coupled to the lead body, the lead body having a proximal section and a distal section, the distal section being thinner and more flexible than the proximal section;

a suture sleeve positioned on the proximal end of the or each lead body; and

a stabilizing block positioned on the distal end of the or each lead body, the stabilizing block having means for stabilizing the or each of the electrode portions of the lead from moving out of position once it/they has/have been implanted while other leads are being implanted.

In the preferred embodiment the semi-cylindrical cuff features one or more electrodes. The semi-cylindrical cuff having a long flap which wraps about the cuff and a short flap which wraps about the long flap. The semi-cylindrical cuff is relatively stiff as compared to the short flap. The short flap, in turn, is relatively the same stiffness as the long flap. The stiffness of each flap may be varied, however, so that one is more or less than the other, and in turn, than the cuff. Through such a multi-flap construction the electrodes may be positioned proximal to a nerve in such a manner that the mechanically induced damage may be minimized or even entirely eliminated. Finally, a method of implanting such an electrode is also disclosed.

The present invention may be better understood and appreciated with reference to a detailed description of a specific embodiment of the invention, given by way of example only, when read in conjunction with the accompanying drawings.

FIG. 1 depicts a system for nerve stimulation featuring several medical electrical leads.

FIG. 2A is a view of the four leads used in the system of FIG. 1 and the anchoring sleeve and anchoring block which secure the leads.

FIG. 2B is a perspective view of a medical electrical lead according to the invention.

FIG. 3 is a detailed view of the electrode portion of

the medical electrical lead.

FIG. 4A is an exploded view of the electrode portion shown in FIG. 3.

FIG. 4B is a sectional view of the electrode portion showing the placement of electrode tabs within the semi-cylindrical cuff.

FIG. 5 is a sectional view of the electrode portion showing the various radial positions of the semi-cylindrical cuff, long flap and short flap.

FIG. 6 is an anchoring sleeve used on the medical electrical lead.

FIG. 7 is an anchoring block used on the medical electrical lead.

FIGS. 8-16 depict a method of implanting the medical electrical lead around the nerve.

FIGS. 17 A, B, and C depict alternative embodiments of the medical electrical lead.

FIGS. 18 A and B depict alternative embodiments of the electrodes used in the medical electrical lead.

FIG. 1 shows a system 1 for nerve stimulation which uses several medical electrical leads of the present invention. As seen, the system features the implantable pulse generator 2 electrically coupled to one or more medical electrical leads 3 by extension cables 4. In the preferred embodiment the pulse generator is the preferred Medtronic model 3025 Sacral Root Stimulator. This device is particularly designed for stimulation of the nerves of the sacral root, although other types of stimulators may also be used. The lead extensions are the Medtronic model 3091 extension cables, although other such devices may also be used. As seen, the system of the preferred embodiment features four medical electrical leads coupled to the implantable pulse generator. The system further preferably features an anchoring sleeve and stabilizing block to maintain the leads in position. These are illustrated below in FIG. 2A.

FIG. 2A is a view of the four leads used in the system of Fig. 1 and the anchoring sleeve and anchoring block which are used to secure the leads. As seen, anchoring sleeve 30 is positioned along the larger diameter section of each lead body of the lead. Positioned distal to the anchoring block is the stabilizing block 35. As seen, the stabilizing block is positioned along the thinner diameter section of the lead bodies of the leads. As discussed below, the suture sleeve functions to secure the leads from moving longitudinally relative to one another once they are implanted. The suture sleeve is fastened to the surrounding tissue as is well known. Stabilizing block 35 functions to stabilize each of the distal sections of the leads in position once they are implanted so that implantation of additional leads and the positioning of their electrodes about a nerve will not disturb those leads and electrodes already positioned.

FIG. 2B is a detailed view of a single medical electrical lead 3 according to the present invention. As seen, the lead has essentially three portions, the connector portion 5, the lead body 6, and an electrode portion 7. The connector portion in the preferred embodiment fea-

tures two pins each of which are electrically coupled to a separate conductor in the lead body. The lead body 6 is preferably constructed of three bundle stranded wire conductors each of which is insulated from the other. The insulation is PTFE, although other types of insulations may also be used, such as silicone.

Positioned at the distal end of the lead body is the electrode portion 7. In the preferred embodiment the electrode portion features three tab electrodes, the inner electrode tab 10 being electrically coupled to a first conductor and the outer two tab electrode tabs 11, 12 electrically coupled to the second conductor of the lead body. In the preferred embodiment the outer two electrode tabs 11, 12 are coupled as anodes while the inner electrode tab 10 is coupled as a cathode. Through this configuration a guarded bipolar electrode is presented to the nerve. A guarded bipolar electrode is preferred because it confines the stimulating current within the electrode cuff and thereby minimizes the undesired spread of current to the surrounding tissues.

FIG. 3 is a detailed perspective view of the electrode portion. As seen the electrode portion 7 is constructed from three elements. Semi-cylindrical cuff 15 has an inner long flap 16 mounted to the root portion 18 of the cuff so as to extend about the opening of the semi-cylindrical cuff. Due to the orientation of the long flap relative to the semi-cylindrical cuff, the lumen is defined. Enveloping the outer end portion of the long flap, is an outer short flap 17. Through this configuration the self-sizing cuff is formed which permits the cuff to stay mounted around the nerve and not be dislodged through the swelling of the nerve. Positioned within the interior surface of the semi-cylindrical cuff are three tab electrodes (only one of which is seen as 12.)

FIG. 4A is an exploded view of the electrode portion. As seen, the electrode portion features a semi-cylindrical cuff. The semi-cylindrical cuff has three cylindrical grooves 20-22 on the inner surface. Three tab electrodes 10-12 are positioned in the grooves. The tab electrodes are preferably constructed from a platinum-iridium alloy, although other materials may also be used such as a conductive polymer. Extending in the opposite radial direction of the semi-cylindrical cuff 15 is the long flap 16. The long flap has a cylindrical design. Extending in the same direction of the semi-cylindrical cuff (and thus opposite radial direction of the long flap) is the short flap 17. The short flap also has a cylindrical shape. In the preferred embodiment the semi-cylindrical cuff is relatively stiff as compared to the short flap. The short flap, in turn, is relatively more stiff than the long flap. Of course, the relative stiffness of the flaps in the cuff may be different. Located at the radial distal end of the semi-cylindrical cuff is a suture hole 23 which may be used to manipulate the cuff during the implant process, described below.

FIG. 4B is a longitudinal cross-section of semi-cylindrical cuff. As seen, electrode tabs 10, 11 and 12 are positioned within cuff recesses in the cuff. Recesses are

dimensioned such that there is an overlap of material along the edges of each electrode tab. Through this overlap the electrode tab is mechanically secured within the cuff. In the preferred embodiment overlap area is 0.5cm (0.2 inches) in length on each side and the exposed area is 1.5cm (0.6 inches) in length. Each electrode tab is positioned in the recess to a depth corresponding to the centre of the cuff thickness.

FIG. 5 shows the relative radial orientations of the flaps and the semicylindrical cuff. As seen, the semicylindrical cuff 15 extends for approximately 180°, although other radial lengths may also be used, including from 270° to 90°. Moreover, although depicted in the figures as a cylindrical design, this cuff may also have other designs, such as square or octagonal, for example, and may also be of other designs entirely, such as helical. The long flap 16 preferably extends in a radial direction opposite that of the semicylindrical cuff for an amount of 340°, although other radial lengths may also be used, such as between 360° - 180°. The short flap 17, in turn, extends in the same radial direction as the semicylindrical cuff and preferably extends for a radial distance of 120°, although other radial distances may also be used, including anywhere between 45° - 360°. Through this construction, the relative radial directions and distances of the semicylindrical cuff and the flaps, as well as through various stiffnesses, the self-sizing property of the electrode portion is provided. The self-sizing property is an essential aspect of the present invention because it permits the electrode to accommodate swelling of the nerve without damaging the nerve while maintaining electrical contact. Moreover, partial dislodgement due to pulling or movement of the electrode portion from the nerve is automatically controlled through the elastic property of the flaps, i.e. the electrode re-seats itself back onto the nerve it has partially dislodged.

FIG. 6 is the suture sleeve used in the system of FIG. 1 and clearly shown in FIG. 2A. As seen, the suture sleeve 30 has a body 31 having a lumen 32 there-through. The lumen is shaped to accommodate four cylindrical lead bodies therein although fewer lead bodies can also be positioned therein. The suture grooves 33 on the body permit the body to be cinched or tied to the lead bodies. The suture hole 34 permits the body to be sutured to the surrounding tissue. The suture sleeve functions to secure the leads from moving longitudinally as indicated by arrow 198.

FIG. 7 depicts the stabilizing block used in the system of FIG. 1 and clearly shown in FIG. 2A. The stabilizing block 35 preferably has four slots 36-39 to accommodate four lead bodies. Slots are accessed by the four leads by bending block in direction 44. Slots are dimensioned in their bottom to correspond to and frictionally engage with lead body although they may also have other shapes, e.g. rectangular. Tabs 40 extend from the block to permit the block to be sutured into the surrounding tissue using holes 41. Stabilizing block stabilizes

each of the electrode portions 7 of each lead from moving out of position while the outer leads are implanted.

FIGS. 8-16 depict the method of implanting a lead according to the present invention. As seen in FIG. 1, the nerve 50 is surgically exposed and elevated from its position using two nerve hooks 51. As seen in FIGS. 9 and 10 forceps 52 are used to gently pull the short flap 17 from its biased position while holding the electrode portion 7 by the lead body. Next, using another pair of forceps 53 the long flap 16 is gently removed from its biased position so the opening of the half cuff 15 is exposed.

Turning to FIG. 13, using the two forceps, 52, 53 the two flaps 16, 17 are moved in opposite linear directions in order to incline the half cuff and present the tab electrodes for contact to the nerve. This is depicted in FIG. 14. Once correctly positioned, the long flap is released and permitted to extend back to its original position around the cuff. Once correctly positioned, the short flap is then released to wrap about the exterior of the long flap. [See Fig. 15]

FIG. 16 shows an alternative method of presenting the tab electrodes to the nerve. In this method a single forceps 60 is used to hold the flaps 16, 17 and a suture 61 is strung through the semicylindrical cuff suture hole. The suture is then used to manipulate the cuff so that the tab electrodes are properly positioned about the nerve. Once the electrode portion is properly positioned, the nerve is released, the lead body and conductor are properly positioned and contacted to the stimulator and the incisions are closed, as well known.

FIGS. 17 A, B and C disclose alternative embodiments of the electrode portion. FIG. 17A shows a semicylindrical cuff 15 having a long flap 16 which is substantially 360° in length and a short flap which is substantially 135° in radial length. The cuff 15 is approximately 90° in radial length. Suture hole portion 14 of cuff is shaded and it does not contribute to the actual radial length of cuff 15. FIG. 17B is a further alternative embodiment in which the cuff 15 has a radial length of 180°, the long flap 16 has a radial length of 270° and the short flap 17 has a radial length of 180°. FIG. 17C is a further alternative embodiment in which the cuff 15 has a radial length of 270°, the long flap 16 has a radial length of 180° and the short flap 17 has a radial length of 270°.

FIGS. 18A and B depict alternative embodiments of the electrodes used in the medical electrical lead of the present invention. FIG. 18A is a view of a semicylindrical cuff 116 shown as if it was flattened into one plane. Of course, cuff 116 is meant to be cylindrical in use and is illustrated only as a plane for purposes of clearly showing the electrode tab configuration. As seen, tabs are disposed longitudinally along cuff 116, the inner electrode tab 110 being electrically coupled to a first conductor and the outer two electrode tabs 111, 112 electrically coupled to a second conductor within a lead body 106. Turning now to FIG. 18B a further alternative embodiment is shown. As seen in this embodiment, in-

ner electrode is composed of two or more electrode areas 210A and 210B. Outer electrode areas are comprised by two or more electrode areas 212A, 212B and 211A and 211B respectively. Areas 210 are coupled to a first conductor in the lead body 206 while areas 212 and 211 are coupled to a second conductor in the lead body. In this embodiment the surface area of the electrode areas 212 and 211 added together equal the total surface area of electrode 210. In each of the embodiments shown in FIG. 18B the electrodes may be formed from a bio-compatible metal, such as a platinum iridium alloy, but may also be formed from a conductive polymer.

Although the invention has been described in detail with particular reference to a preferred embodiment and alternative embodiments thereof, it will be understood variations and modifications can be effected within the scope of the following claims.

Claims

1. A medical electrical lead comprising a lead body (6) having a conductor covered by an insulator, the lead body having a proximal end and a distal end; means (4) for connecting the lead body to a pulse generator (2), the connecting means coupled to the proximal end of the lead body, a cuff assembly coupled to the distal end of the lead body, the cuff assembly having a root portion (18), a semi-cylindrical cuff (15) extending from the root portion in a first radial direction and a long flap (16) extending from the root portion in a second radial direction, the long flap (16) extending over at least a portion of the semi-cylindrical cuff (15).
2. A medical electrical lead comprising: a lead body (6) having a conductor covered by an insulation, the lead body having a proximal end and a distal end; a cuff assembly coupled to the distal end of the lead body, the cuff assembly having a semi-cylindrical cuff (15) having at least one recess (20,21,22) therein, a tab electrode (10,11,12) positioned at the bottom of the or each recess (20,21,22), the tab electrode coupled to the conductor.
3. A medical electrical lead according to claim 2 wherein the or each recess (20,21,22) extends from an inner surface of the cuff (15) to a depth corresponding to the midpoint of the cuff thickness, the tab electrode (s) (10,11,12) positioned at the midpoint of the cuff thickness at the bottom of the or each recess.
4. A medical electrical lead according to claim 2 or 3, wherein the cuff assembly comprises a root portion (18), the semi-cylindrical cuff (15) extending from the root portion (18) in a first radial direction, a long flap (16) extending from the root portion in a second radial direction, the second radial direction opposite the first radial direction.
5. A medical electrical lead according to claim 4 wherein the long flap (16) extends over at least a portion of the semi-cylindrical cuff (15).
6. A medical electrical lead according to claim 1, 4 or 5 wherein the first direction is opposite the second direction.
7. A medical electrical lead according to claim 1, 4, 5 or 6, wherein the first radial direction is between 90 and 270 degrees.
8. A medical electrical lead according to any of claims 1 or 4 to 7, wherein the second radial direction is between 180 and 360 degrees.
9. A medical electrical lead according to any of claims 1 or 4 to 8 further comprising a short flap (17) extending from the root portion (18) in the first radial direction.
10. A medical electrical lead according to any of claims 1 or 4 to 9 further comprising a short flap (17) extending over the semi-cylindrical cuff (15).
11. A medical electrical lead according to claim 9 or 10 wherein the semi-cylindrical cuff is relatively more stiff as compared to the short flap.
12. A medical electrical lead according to any of claims 9 to 11 wherein the short flap is relatively more stiff than the long flap.
13. A medical electrical lead according to claim 1 or any claim dependent thereon wherein the means for connecting the lead body to a pulse generator comprise a connector assembly.
14. A system for providing medical electrical stimulation comprising: one or more medical electrical leads (3) having a lead body (6) and an electrode portion (7), the electrode portion coupled to the lead body, the lead body having a proximal section and a distal section, the distal section being thinner and more flexible than the proximal section;
 - a suture sleeve (30) positioned on the proximal end of the or each lead body (3); and
 - a stabilizing block (35) positioned on the distal end of the or each lead body, the stabilizing block having means (36,37,38,39) for stabilizing the or each of the electrode portions of the lead from moving out of position once it/they has/have been implanted while other leads are

being implanted.

15. A system according to claim 14 wherein the means of stabilizing comprise a pliant polymer block having one or more series of slots (36,37,38,39), the slot (s) dimensioned to frictionally engage with the or each lead body (3). 5
16. A system according to claim 14 or 15 wherein the or each medical electrical lead comprises a lead as defined in any of claims 1 to 13. 10

15

20

25

30

35

40

45

50

55

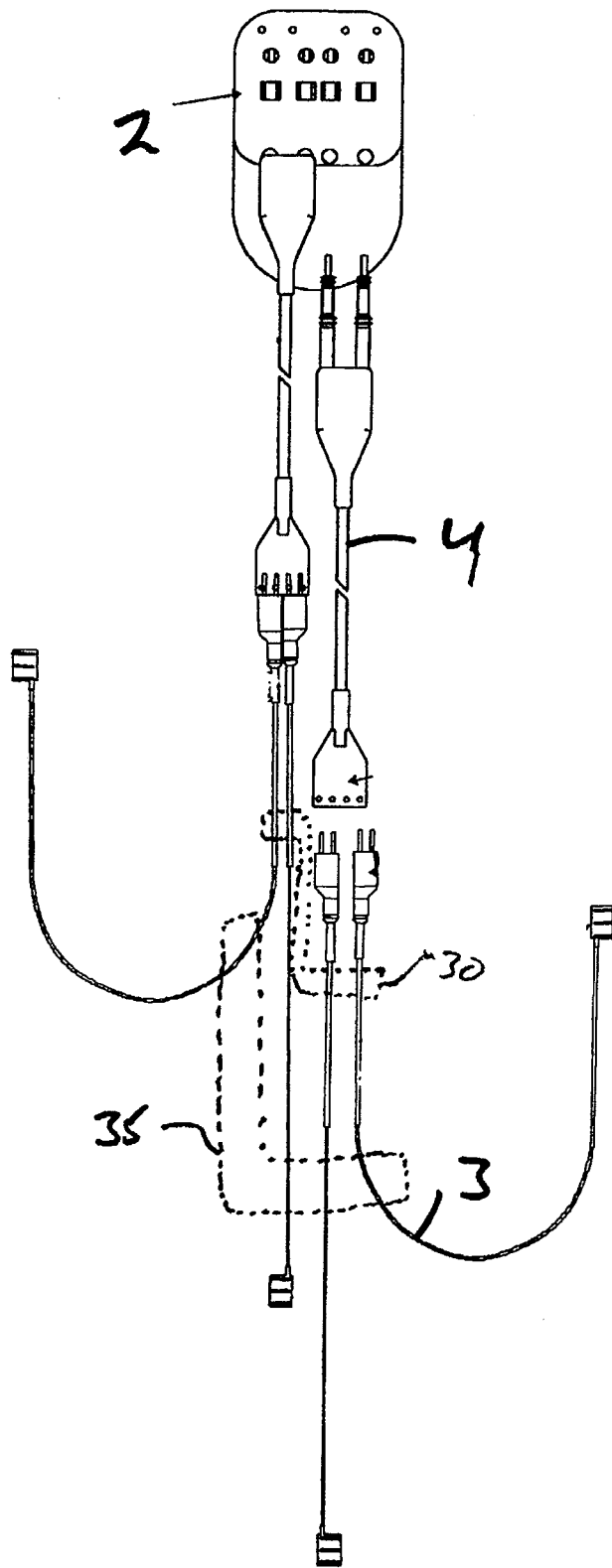
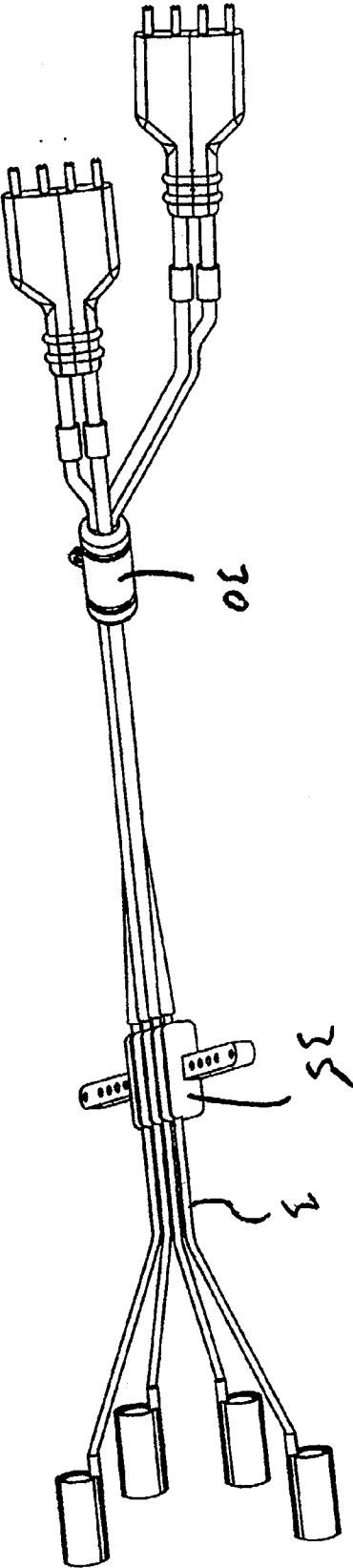


Fig 1

FIG 2A



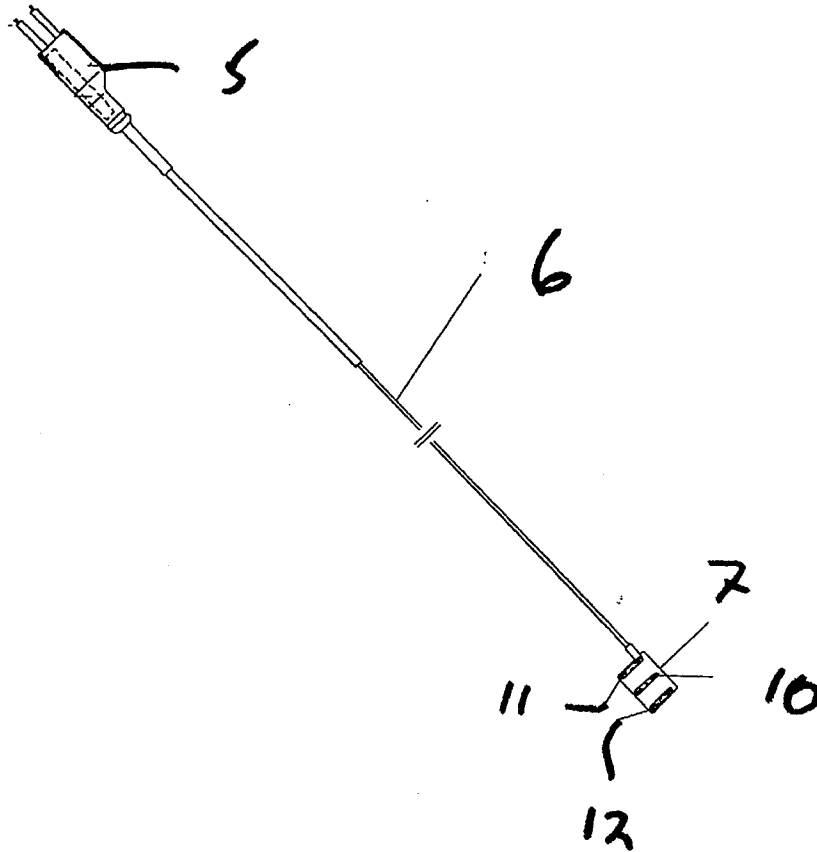
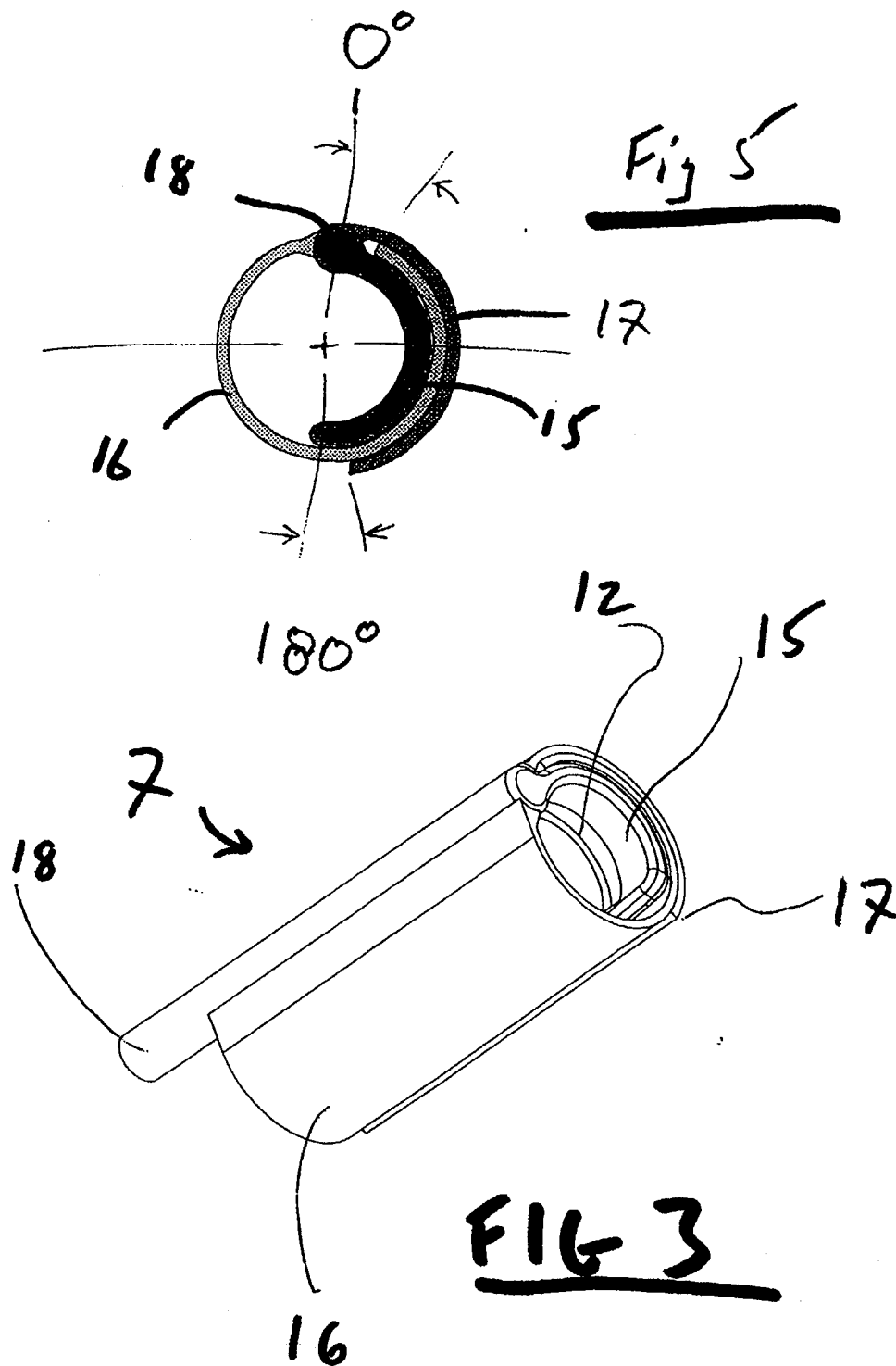


Fig 2B



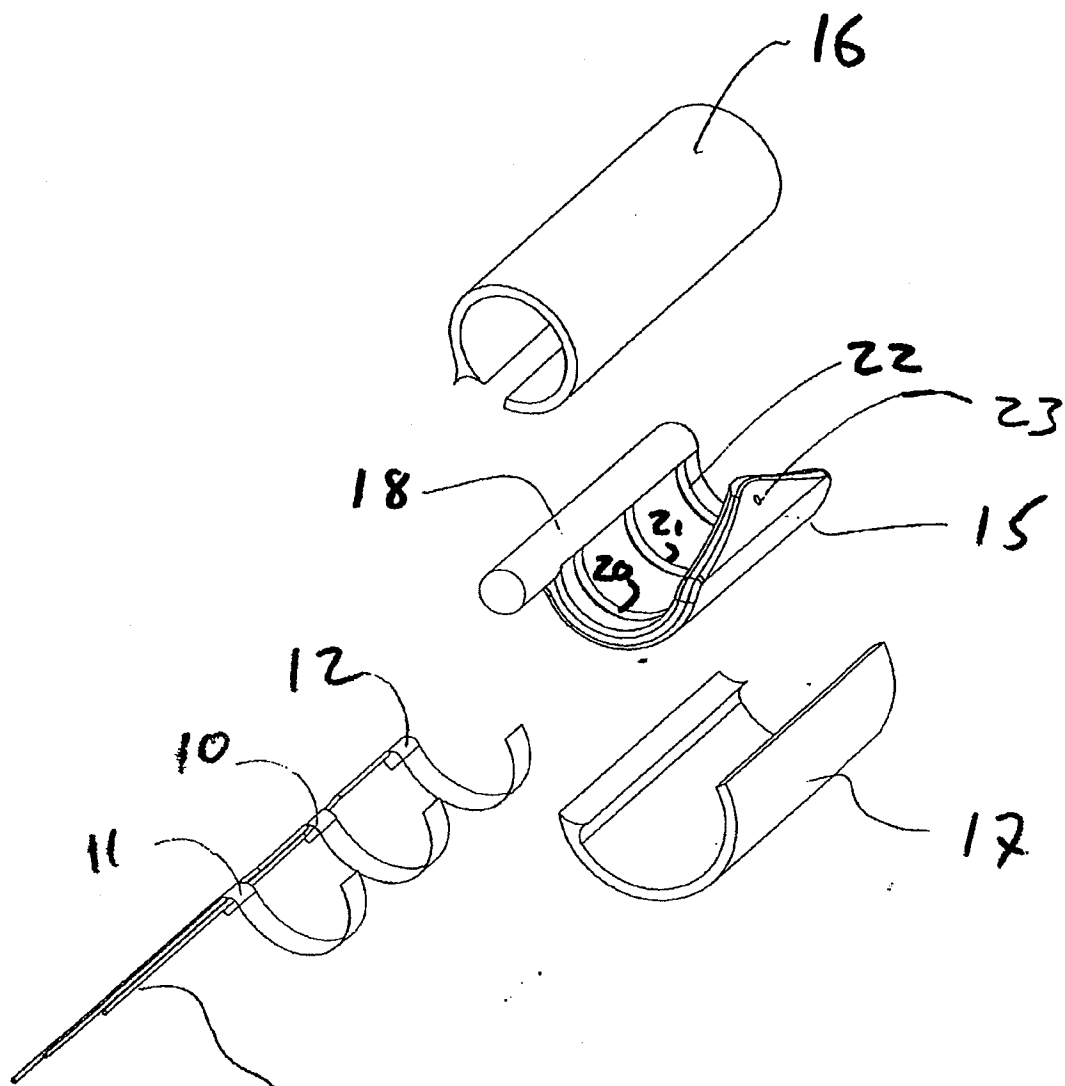


Fig 4A

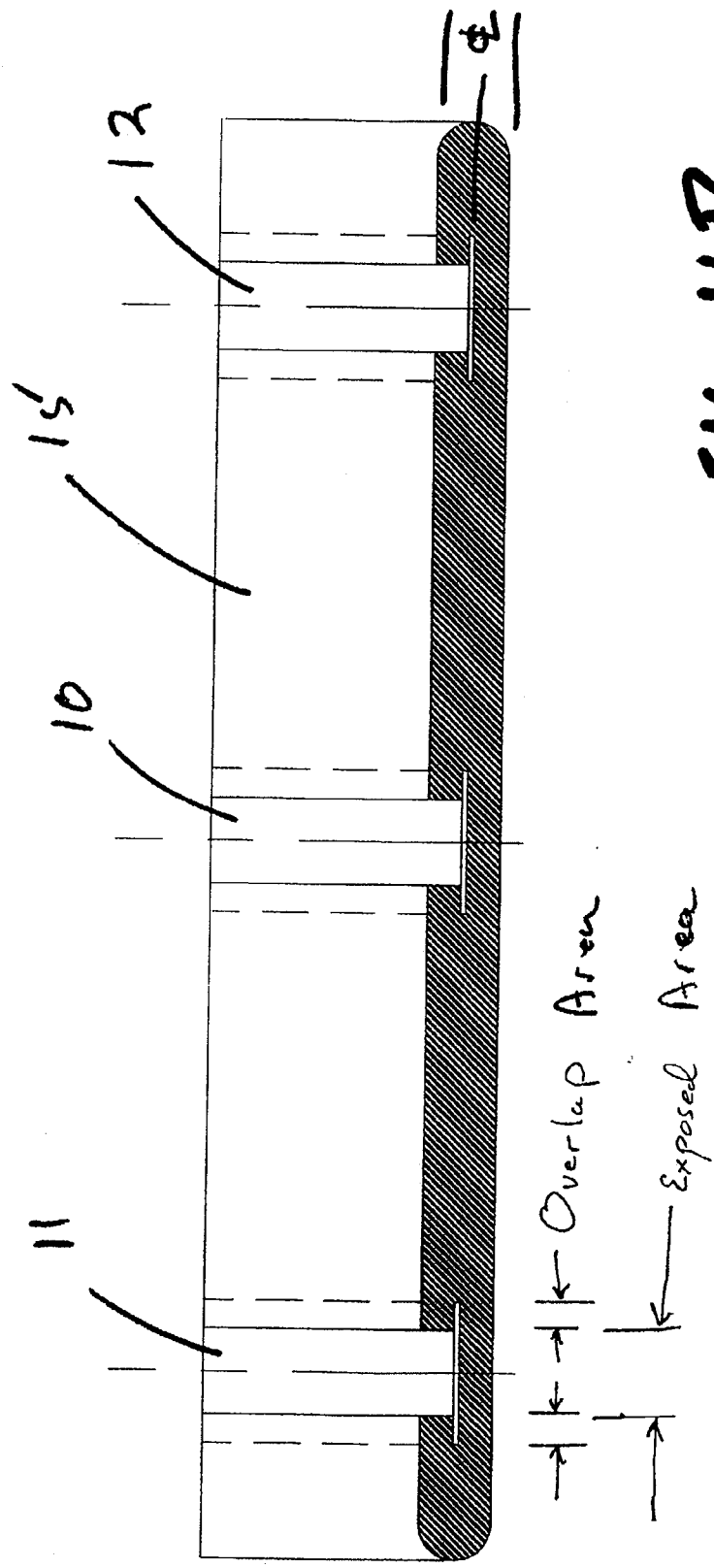
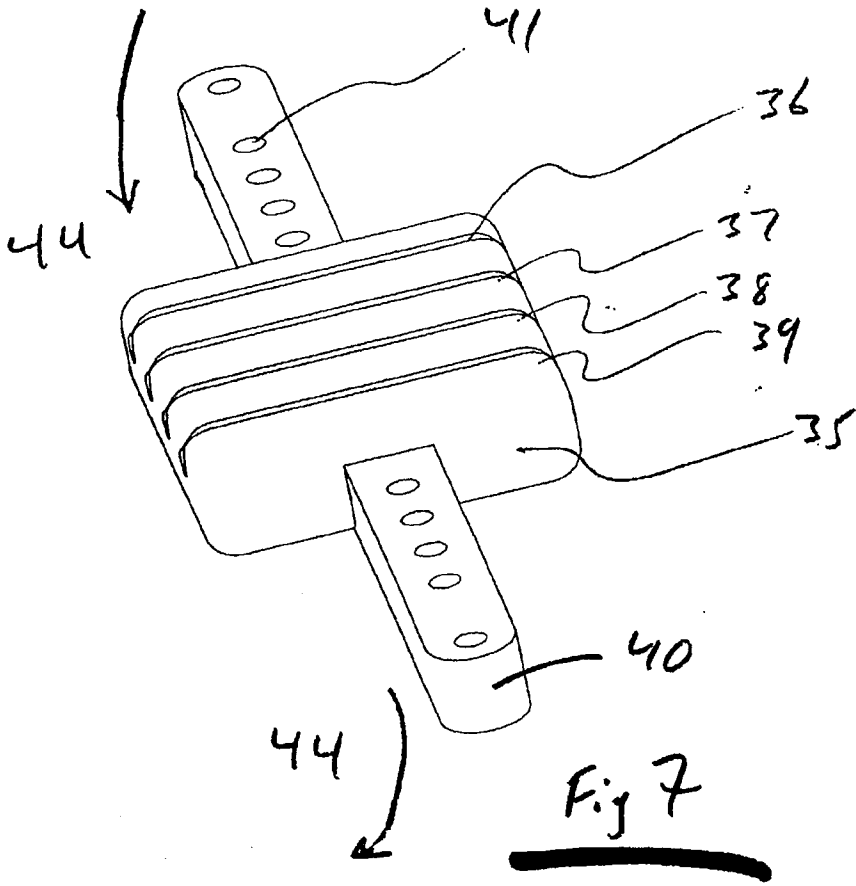
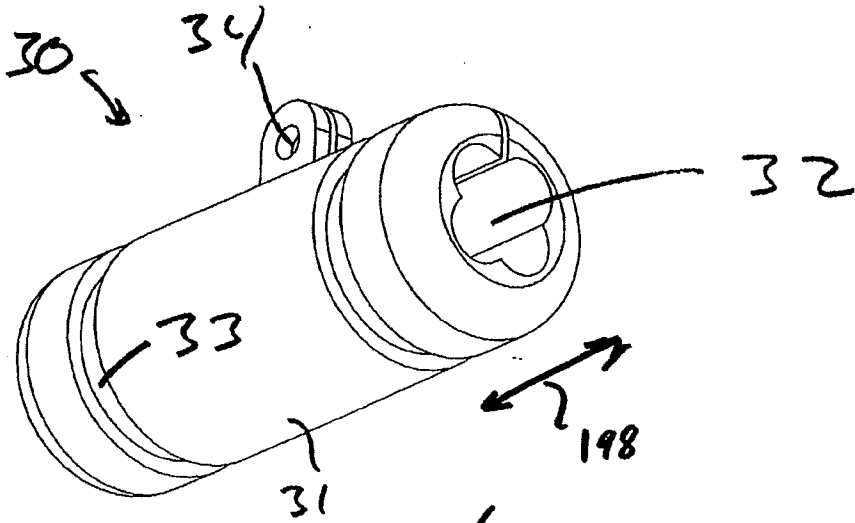


FIG 4B



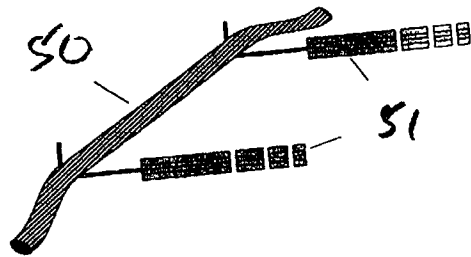
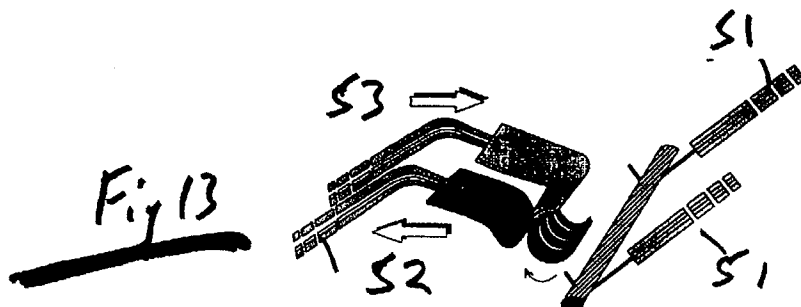
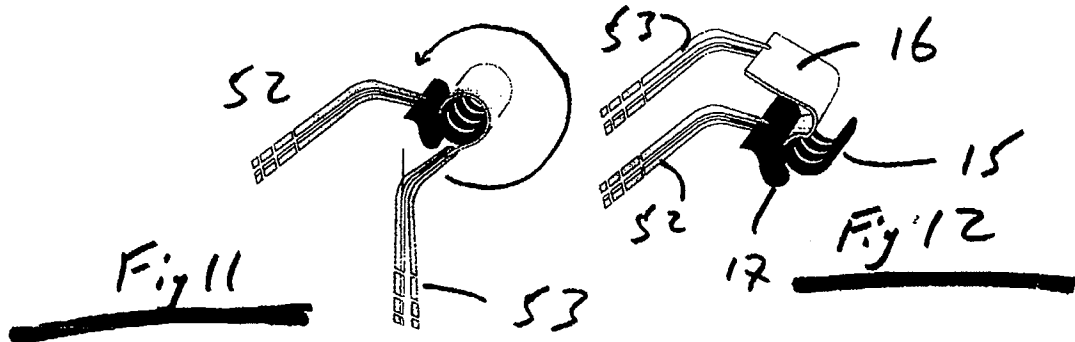
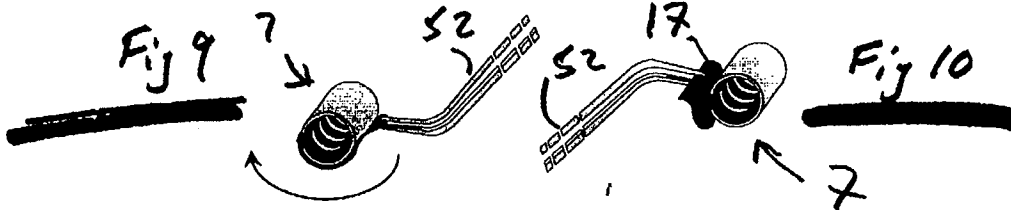


Fig 8



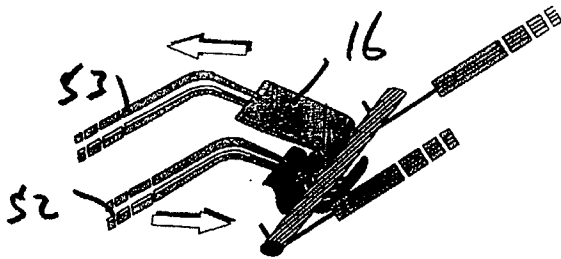


Fig 14

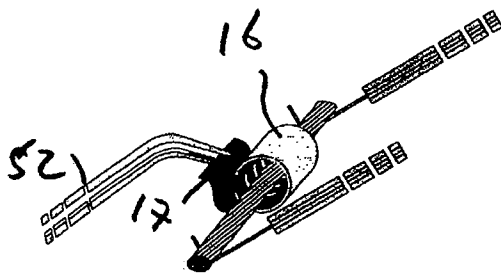


Fig 15

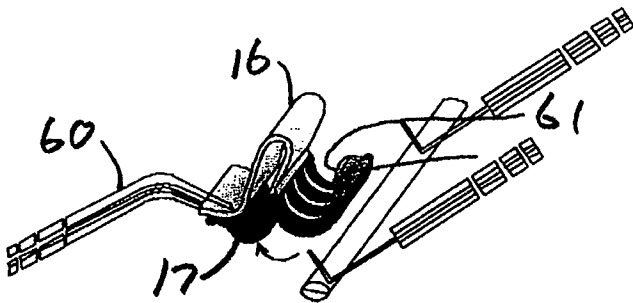


Fig 16

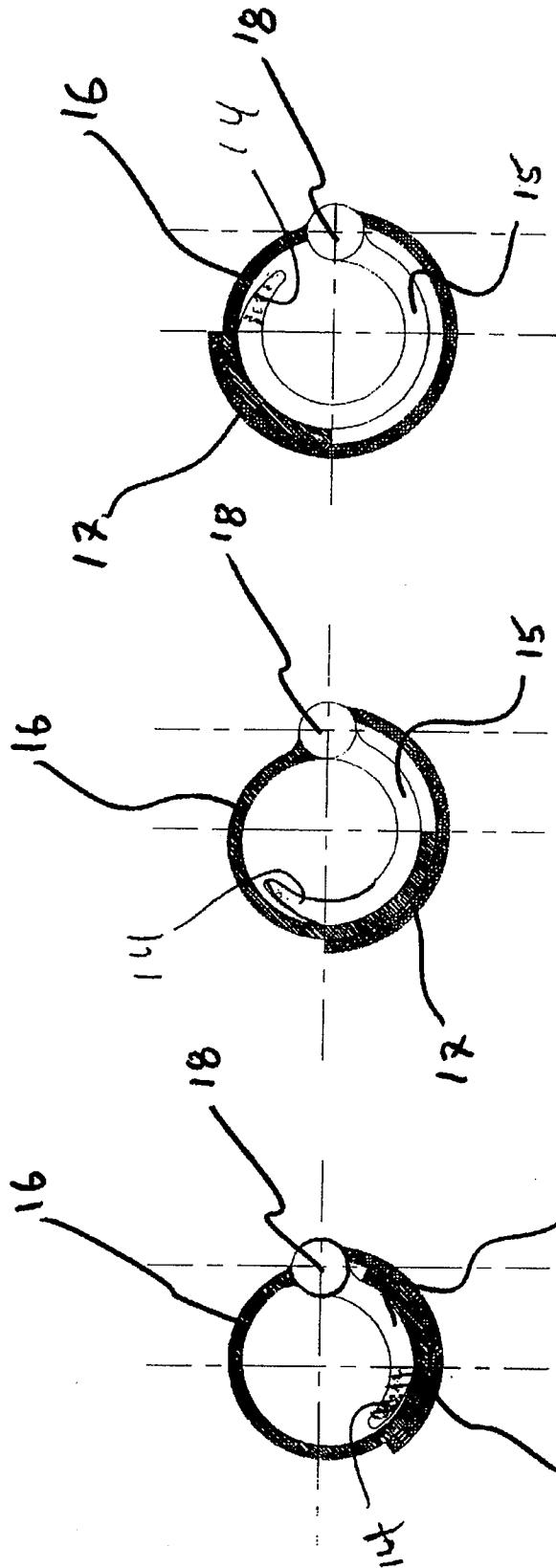


FIG 17C

FIG 17B

FIG 17A

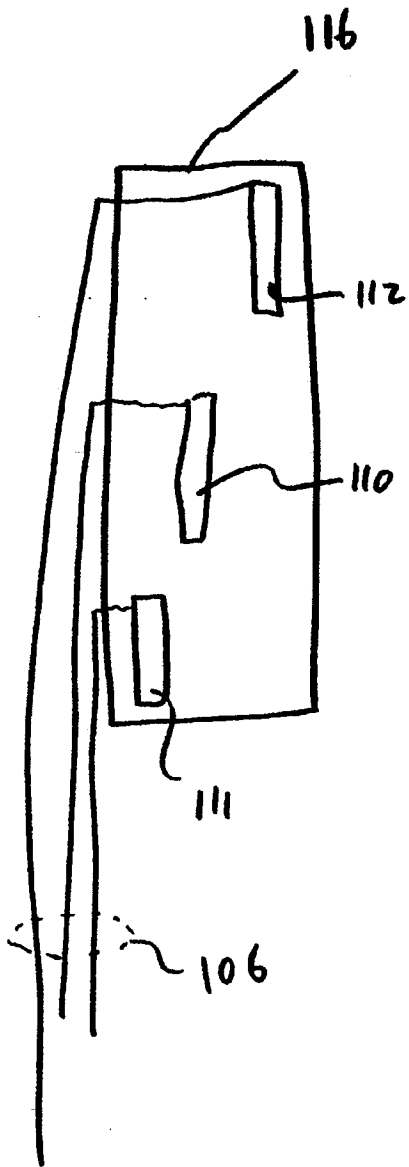


FIG 18A

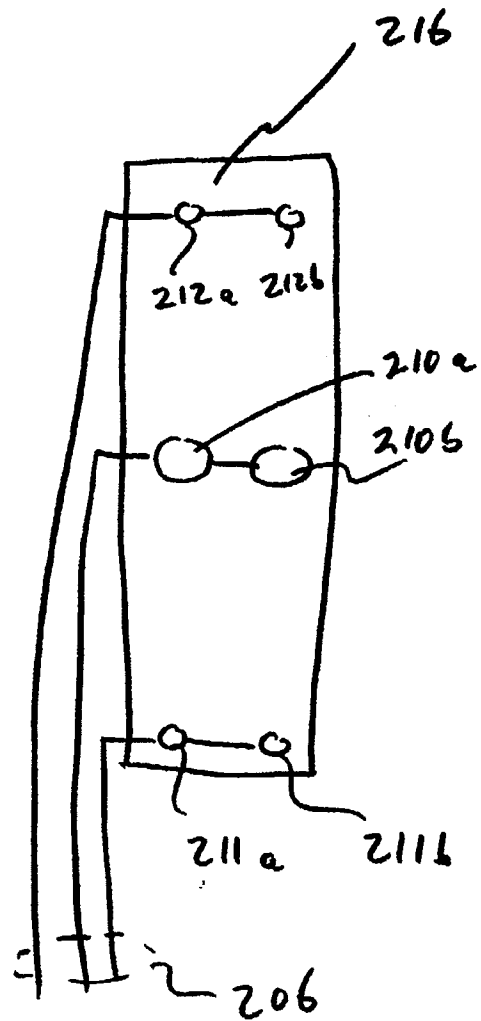


FIG 18B